

REMARKS

1. Applicants canceled, without prejudice, certain claims to facilitate prosecution. Applicants are grateful for the suggestions of the Examiner, which were adopted. Nucleotides of certain size are taught at page 55, first full paragraph of the instant application. Features of an ATP binding cassette protein of interest are provided at page 1, last full paragraph and most of page 3 of the instant specification. Hence, no issue of new matter arises and entry of the amendments is requested respectfully.

2. On page 3 of the Office Action, the Examiner mentioned a defective CRF of the Sequence Listing. Unfortunately, the Error Report of 19 August 2004 is not available.

In any event, attached hereto is another CRF, the content of which is the same as that of the paper copy of record.

3. Claims 1-9, 12, 13, 16-25, 31, 32 and 40-63 were rejected under 35 U.S.C. §§ 101 and 112, first paragraph. The Examiner believed the claims are not supported by a specific and substantial asserted utility or a well established utility and thus, also are not enabled.

The two rejections are traversed for the following reasons.

The Lefevre et al. reference of record affirms the teachings of the instant application. Lefevre et al. found the ABCA12 gene is correlated with lamellar ichthyosis, as taught at page 9, first full paragraph, and Lefevre et al. found the gene ABCA12 is expressed in skin, as taught in the instant application in that same passage. As is known in the art, a suitable place to find a functional mutation is to focus, for example, on evolutionally conserved regions of a protein or in functional domains of a protein. In the case of ABCA12, an artisan would be directed to look for functional mutations in the ATP binding portion of the molecule, page 8, second full paragraph, and that is what Lefevre et al. confirmed.

Moreover, lamellar ichthyosis is an autosomal recessive disorder, page 7, line 22 of the specification. Therefore, with two defective alleles, an artisan would well recognize that it is likely introduction of a normal, expressed allele is a suitable course of gene therapy, as taught in the instant specification, paragraph bridging pages 66 and 67.

As provided in the instant specification, a normal gene can be placed into a desired cell, for example, a skin stem cell, to obtain expression of a functional ABCA12 protein, using any of the many methods set forth in the instant application at pages 39-49 and 61-76. The nucleic acid of interest can be used to identify abnormal alleles, page 57, 3rd and 4th full paragraphs. The application teaches a number of nucleic acid assays to detect ABCA12 genomic DNA, mRNA, cDNA and the like, for detecting a mutant or polymorphism using methods known in the art, pages 54-61. The specification teaches labeling an ABCA12 probe or primer of interest obtained from the four clones of interest, for example, in diagnostic assays or to retrieve additional clones, page 54, first full paragraph. The probes of interest can be used in PCR amplification assays to identify mismatches, page 54, fourth full paragraph. The nucleic acids of interest also can be expressed and then used to identify agonists and antagonists of ABCA12, pages 87-91 of the application.

The instant application also enable teaches use of a polypeptide expressed therefrom for obtaining antibodies thereto, which antibodies can be used for therapeutic and diagnostics purposes, as known in the art, page 76-82 of the instant application.

Clearly, the instant application, and hence the claims, provide a number of specific, substantial and credible uses of the nucleic acids of interest. The specification teaches thoroughly how to make and how to use a nucleic acid of interest. Therefore, utility exists and a prima facie case of non-enablement has not been made. Accordingly, withdrawal of the §101 and §112, first paragraph rejections is requested respectfully.

4. At the top of page 5 of the Office Action, the Examiner rejected claims 2-5 and 41-51 under §112, first paragraph, stating that the specification does not enable polynucleotides that are 80%-98% identical to SEQ ID NOs: 1, 2, 3, or 4, polynucleotides that hybridize with a nucleotide sequence comprising at least 8 consecutive nucleotides of SEQ ID NOs: 1, 2, 3, or 4, or polynucleotides that hybridize with a nucleotide comprising SEQ ID NOs: 1, 2, 3, or 4.

The rejection is traversed for the following reasons.

The specification speaks at length about methods to produce ABCA12 nucleotide derivatives resulting in fragments or sequences that are at least 80-98% identical to the sequences

of SEQ ID NOs: 1, 2, 3; and 4. Thus, for example, a number of primers and probes are disclosed, see Table 3 on page 56 of the instant application.

Moreover, it is known that ABCA genes have particular characteristics and that the polypeptides encoded thereby also have certain particular characteristics. Methods for identifying those distinguishing characteristics are known in the art. Thus, methods for detecting ATP binding are known. The consensus characteristics of transmembrane domains are known. Also, the characteristics that define an ABCA member are known.

Therefore, an artisan can readily determine whether a fragment or a sequence not identical to one of the four lengthy sequences of interest nevertheless is related to an ABCA12 polynucleotide of interest.

Accordingly, claims 2-5 and 41-51 are enabled and in compliance with the statute. Withdrawal of the rejection is in order.

5. At the top of page 6 of the Office Action, claims 2-5 and 41-51 were rejected under 35 U.S.C. § 112, first paragraph for an alleged want of written description.

The rejection is traversed for the following reasons.

As provided in the enablement discussions hereinabove, and herein incorporated by reference, an artisan would recognize on reading the instant application, based on the state of the art, that modifications can be made to a nucleic acid as claimed without departing from the spirit and scope of the invention. As detailed hereinabove, the instant application clearly and thoroughly describes the many uses of a nucleic acid of interest. For example, methods of gene therapy, diagnosis based on hybridization and amplification as well as screening assays for agonists and antagonists are set forth in detail in the specification. That artisan would have recognized and known that the inventors had made the invention claimed.

Thus, the written description requirement being satisfied, withdrawal of the rejection is in order.

6. Halfway down page 6 of the Office Action, claims 2, 5, 7, 9, 13, 16 and 17 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The issue relates to new matter.

The rejection has been overcome.

7. Beginning at the bottom of page 6 of the Office Action, the Examiner rejected claims 1-9, 12, 13, 16-21, 31 and 41-63 under 35 U.S.C. § 112, second paragraph.

Applicants thank the Examiner, her suggestion was adopted and hence, withdrawal of the rejection is requested respectfully.

8. On page 7 of the Office Action, the Examiner rejected claims 48-51 under 35 U.S.C. § 112, second paragraph.

In light of the amendment, withdrawal of the rejection is in order.

9. At the bottom of page 7 of the Office Action, the Examiner rejected claims 2, 5, 7, 16, 44, 45, 48, 49, 52, 53, 60 and 61 under 35 U.S.C. § 102(b) as allegedly being anticipated by the GenBank sequence of Ansorge et al.

The rejection is traversed for the following reasons.

The GenBank sequence of Ansorge et al. relates to a particular partial nucleic acid sequence. That GenBank sequence neither teaches nor suggests isolated nucleic acids larger or smaller than that specific sequence.

Thus, there is no anticipation and the rejection can be removed.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the objections and rejections, and early indication of allowance are requested respectfully. Should the Examiner believe that an interview would advance the prosecution of the instant application, Applicants invite her to contact the undersigned at the local exchange noted below. The Commissioner is authorized to credit or debit Deposit Account No. 29180 if needed as relating to this paper to maintain pendency of the instant application. Finally, the undersigned avers having authority to act on behalf of applicants and the real parties in interest. A Revocation will be filed shortly. In the meantime, please revise the PTO correspondence address for the above-captioned application to that below.

Respectfully submitted,

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